REMARKS

Reconsideration and withdrawal of the rejections of the application are requested in view of the amendments and remarks presented herein, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-6, 12-18 and 47-52 are under pending in this application. Claims 1, 6, 14, 16 and 18 are amended; claims 47-52 are added. Support for the claim amendments can be found throughout the specification. Particular support for the recitation "retinal or choroidal neovascularization" can be found, for example, on page 3, line 4. Support for an EIAV-based lentiviral vector can be found, for example, on page 7, lines 17-18. Support for direct administration can be found, for example, on page 7, line 2. Support for claim 47 can be found, for example, in the section beginning on page 12, line 14, page 15, lines 7-8, and page 17, lines 9-10. Support for claim 48 can be found, for example, on page 4, lines 28-31, page 52, lines 28-30, and page 53, lines 8-18. Support for claim 49 can be found, for example on page 9, line 5. Support for codon optimization, as recited in claims 50-52 can be found, for example, in Figures 5 and 6 and the descriptions thereof on page 11. No new matter is added.

It is submitted that the claims are patentably distinct over the prior art and that these claim are and were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE REJECTION UNDER 35 U.S.C. § 112, 1ST PARAGRAPH, IS OVERCOME

Claims 1-18 were rejected under the first paragraph of Section 112 as allegedly lacking enablement. The rejection is traversed.

The claims are directed to EIAV-mediated angiostatic gene delivery to the eye for treating retinal or choroidal neovascularization. The specification describes EIAV-based lentiviral vectors that are ideally suited for gene therapy of eye disease. Due to the favorable cellular tropism and expression kinetics of EIAV-based lentiviral vectors, these vectors can mediate rapid, stable, highly efficient transgene expression in a variety of ocular cells after intraocular administration. Example 4 describes the construction of EIAV-based lentiviral vectors comprising

polynucleotides encoding various angiostatic genes, such as endostatin and/or angiostatin, in operable linkage with physiologically regulated promoters, such as the HRE promoter, as well as constitutive promoters, such as the CMV promoter.

In addition, by following the teachings of the specification, Applicants have demonstrated, in an art-recognized animal model of choroidal neovascularization (CNV), that delivery of EIAV-based lentiviral vectors carrying endostatin or angiostatin results in significant and comparable inhibition of both angiogenesis and vascular hyperpermeability. See Balaggan *et al.*, Gene Therapy (2006), 13:1153-65; copy enclosed. Using the teachings of the specification, Applicants have also conducted a long term study demonstrating delivery of EIAV-based lentiviral vectors intraocularly. The study shows that these vectors produce efficient, long-term gene expression in different ocular tissues through different routes of intraocular delivery. See Balaggan *et al.*, Journal of Gene Medicine (2005), 8(3):275-85; abstract and preprint enclosed.

Accordingly, the claims are enabled for their full scope. Reconsideration and withdrawal of the enablement rejection are requested.

III. THE ART REJECTIONS ARE OVERCOME

Claims 1, 2, 5-8 and 12-15 were rejected under Section 102(b), as allegedly being anticipated by Honda *et al.*

Claims 1, 2, 5-8 and 12-15 were rejected under Section 102(b), as allegedly being anticipated by Gehlbach *et al.*, 2002.

Claims 1, 2, 6-8 and 12-15 were rejected under Section 102(a), as allegedly being anticipated by Takahashi *et al.*

Claims 1, 2, 6-10 and 12-15 were rejected under Section 102(b), as allegedly being anticipated by Igarashi *et al.*

Claims 1, 2, 5-8 and 12-15 were rejected under Section 102(b), as allegedly being anticipated by Mori *et al.*

Claims 1, 2, 6-10 and 12-15 were rejected under Section 102(b), as allegedly being anticipated by Mori *et al.*

Claims 1, 2, 5-10 and 12-18 are rejected under Section 102(b), as allegedly being anticipated by Kovesdi *et al.*

Claims 1 and 16-18 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Takahashi *et al.* in view of Semkova *et al.*

None of the cited references, alone or in any combination, teach or suggest a method for treating retinal or choroidal neovascularization by administering an EIAV-based lentiviral vector comprising an angiostatic gene. Therefore, the claims are not anticipated and reconsideration and withdrawal of the rejections are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: Anne-Marie C. Yvon

Thomas J. Kowalski
Reg. No. 32,147

Anne-Marie C. Yvon, Ph.D.
Reg. No. 52,390
Tel (212) 588-0800